IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	MCCLURKEN	Examiner:	M. F. PEFFLEY
Serial No.:	10/773,503	Group Art Unit:	3739
Filed:	February 6, 2004	Docket No.:	13045.20USC1
Confirmation No.:	6627	Customer No.:	23552
Title:	ELECTROSURGICAL DEVICE HAVING A TISSUE REDUCTION SENSOR		

RULE 1.131 DECLARATION OF MICHAEL E. McCLURKEN

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Michael E. McClurken, do hereby declare as follows:

1. I am the inventor of the subject matter claimed in the above-identified patent application (hereinafter "Patent Application").

2. I am providing this Declaration to provide my sworn testimony of when I actually conceived of the invention as claimed in this Patent Application.

3. I understand that the Examiner has cited Bommannan *et al.* (U.S. Patent No. 6,775,575) (hereinafter "Bommannan") as prior art in support of the rejection of at least some of the claims of this Patent Application.

4. I further understand that the Patent Application is a continuation of an earlier U.S. application, U.S. Patent Application Serial No. 09/802,288. U.S. Patent Application Serial No. 09/802,288 was filed on March 8, 2001.

5. I invented the subject matter claimed in the Patent Application before the earliest possible effective prior art date of the Bommannan patent, that is before February 26, 2001.

6. Attached as Exhibit A hereto is an excerpt from a document that summarizes my conception of the subject matter claimed in the Patent Application. This document was created before the earliest possible effective prior art date of the Bommannan patent, that is before February 26, 2001.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and, further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 3/31/08

Michael E. McClurken

BIPOLAR

1. **Forceps with "outrigger" tissue clamps to measure tissue shrinkage.** This is a bipolar device with opposing jaws that are wetted much like the current lung forceps, with a few modifications:

   (1) There are no serrations on the jaws of the active wet electrodes and heated tissue can shrink freely beneath the electrode jaws (in this the "heated zone"),

   (2) There are two "outrigger" tissue clamps astride the electrode jaws (one on each side) that firmly grasp the tissue outside the heated zone,

   (3) Each tissue clamp has serrations or surface roughness on its tissue-grasping jaw surfaces so that motion of the tissue due to shrinkage can be accurately sensed,

   (4) Each outrigger tissue clamp is attached to the main body of the device in a manner that enables accurate measurement of the motion of each tissue clamp as tissue in the heated zone shrinks. For example each tissue clamp could be hinged at it's junction with the main body of the device, so that as each tissue clamp swings inward a pin on the arm of each tissue clamp moves further into the main body of the device, the motion quantified by one of several methods (linear potentiometer, optical sensor, spring/force sensor, etc.)

   (5) The data on the displacements of the tissue clamps is sent to the generator and processed. The generator could "sense" the device automatically (via some coding on it's plug) or otherwise have the width of the active electrode jaws input to the generator. The generator would calculate the % shrink by dividing the sum of the change in both tissue clamps by the width of the active electrode jaws.

   (6) The generator would turn of the RF power when the maximum % shrink was achieved. The maximum % shrink would have been set by a multiple-position switch on the generator (or electronic equivalent).

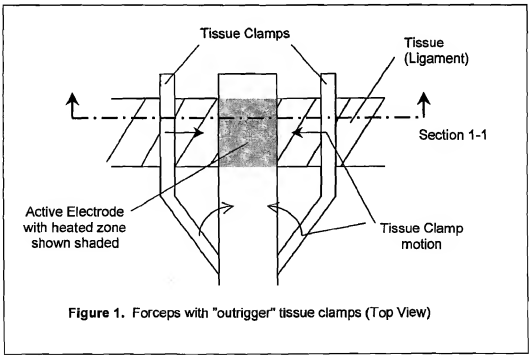

Figure 1. Forceps with "outrigger" tissue clamps (Top View)

Forceps with "outrigger" tissue clamps (continued)

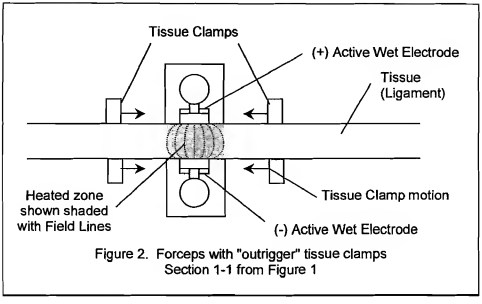

Figure 2. Forceps with "outrigger" tissue clamps
Section 1-1 from Figure 1

This simple drawing illustrates how % shrinkage could be measured directly with the same device that delivers the RF-induced heat. The width of the active electrode would be as large as 5 – 10 mm, so that if the max % shrink was 20-30%, it would be easier to accurately sense total tissue clamp displacements of at least 1 mm, preferably 2 mm or more. Having a wider active electrode would also decrease treatment time.

The outrigger tissue clamps have been shown in Figures 1 and 2 as well apart from the main body of forceps. This is for illustrative purposes only. In practice, they would be much closer to the main body.

Another simple and perhaps more practical embodiment is to have the surgeon preset a mechanical stop on the device before putting the device on tissue. This way the generator would not be needed to act as a controller and all control would be simply in the adjustments made to the mechanics of the device's active distal end.

2. **Dual Active Tissue Clamps with mechanical shrinkage measurement**. This is similar to the outrigger approach, but with each tissue clamp electrified to deliver the RF and move with the tissue to measure the shrinkage.

   (1) Instead of the two jaws (upper and lower) of each clamp being (+) and (–) polarity, one of the clamps has both upper and lower jaws at the same (+) polarity, and the other clamp has both jaws at the same but opposite (–) polarity. Thus the tissue heated is not primarily between the "jaws" but between the pair of clamps.

   (2) Compared to the "outrigger" approach, this device would be simpler (fewer moving parts) and able to apply heat over a larger volume of tissue.

   (3) Each of the two heating clamps would have serrated or roughened jaws to grasp firmly and move with the tissue and it shrinks.

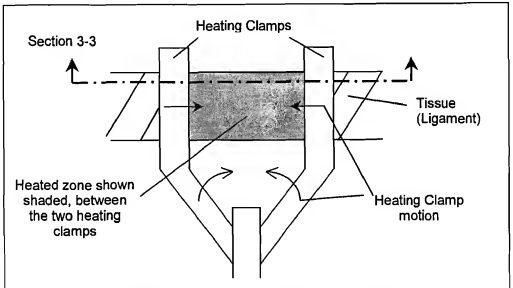

Figure 3. Dual Active Tissue Clamps (Top View)

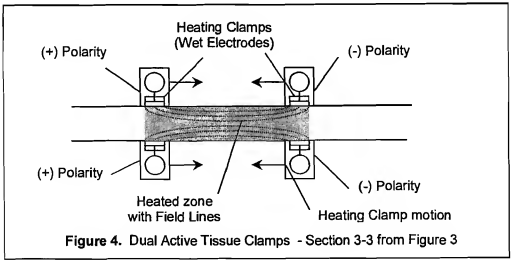

Figure 4. Dual Active Tissue Clamps - Section 3-3 from Figure 3

The use of a pre-set mechanical stop would be most advantageous for this type of device. Use of heated saline (to 37 – 42 °C)may help enlarge the shrink zone by reducing the cooling near each clamp.

3. Dual Active Tissue Clamps with Painted Pattern Visual Indicator of % Shrink. This is almost the same as the previous approach, except that a different technique is used to measure % shrink.

(1) Instead of a mechanical method based on sensing the motion of the arms of the tissue clamps, the surgeon would apply a non-toxic dark ink pattern directly to the ligament.

(2) Assuming the ligament is wide enough, a pattern would be painted on the ligament, such that when the ligament shrinks the painted pattern changes shape.

(3) The pattern could be elliptical, such that at 30% shrink the ellipse becomes a circle.

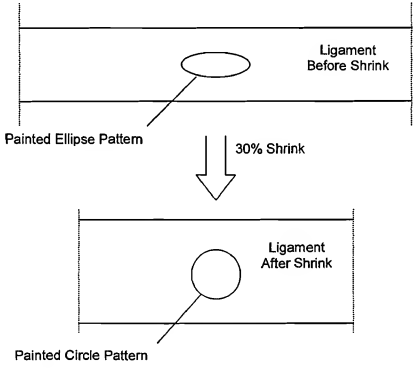

Figure 5. Use of Surface Painted Pattern to Visually Gauge % Shrink

(4) This technique has been applied to "Ace" bandages for wrapping legs to prevent deep vein thrombosis. The goal was to somehow know how tight the bandages were just from looking at the bandages after they'd been stretched.